

REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicant asserts that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims 1-42 are pending in the application. Applicant reserves all rights in these claims to file divisional and/or continuation patent applications

Claims 1-38 have been rejected by the Examiner. Claims 1, 3, 7, 8, 10, 14, 15, 18, 22, 24, 25, 28-30, 32, 35, 37 and 38 have been amended. Claims 4, 6, 11, 13 and 33 have been canceled. Claims 39-42 have been added.

Applicant respectfully asserts that the amendments to the claims add no new matter.

SPECIFICATION AND CLAIM OBJECTIONS

The disclosure was objected to for the reasons set forth on page 3 of the Office Action. Applicant has amended the specification herein and these objections are now moot and should be withdrawn.

Claims 35 and 36 were objected to for the reasons set forth on page 3 of the Office Action. Claim 35 has been amended herein to be dependent on claim 1 and claim 36 is dependent on claim 35. In view of these amendments the objections are moot and should be withdrawn.

CLAIM REJECTIONS

35 U.S.C. § 112, second paragraph Rejections

Claims 1-38 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant

regards as the invention. The following claim terms were pointed out in the Office Action and Applicant addresses herein below:

1. "robust"
2. "deleterious traits"
3. "average content in currently available varieties"

The Office Action states that these terms are considered as relative terms lacking a comparative basis. Applicant respectfully traverses this rejection in view of the remarks that follow.

1. "robust"

It is the Applicant's assertion that the definition of the term "robust" cited in claim 1 is well known in the conventional relevant art. For example, a recent publication of Ruoyu Luoabc et al., (2009): *Photosynthetic metabolism of C3 plants shows highly cooperative regulation under changing environments: A systems biological analysis*, in the academic journal PANS, investigated robustness of photosynthetic metabolism in the chloroplasts of C3 plants under drought stress and at high CO2 concentration conditions. This publication provides the acceptable definition of the term robustness, as follows:

"As a general definition, robustness is a property that maintains system function in the face of various perturbations (13, 14). It is one of the inherent properties of biological systems. In particular, aspects of the mechanism and the origin of robustness have been investigated, for instance, the topology of networks such as the bow-tie structure of biological systems (15), feedback control (16), robustness tradeoffs such as Highly Optimized Tolerance (HOT) theory (17), duplication of pathways (18), and decoupling pathways (19). More recently, Kitano has suggested how to describe the robustness of biological systems quantitatively (20)."

It is further emphasized that the authors of this publication state that a tentative quantitative definition of robustness has been suggested only recently (Kitano H, 2007, towards a theory of biological robustness. Mol Syst Biol 3:137), well after the first publication of the

current application which is Jan. 29, 2004. Thus robust is a well known term to describe a healthy, vigorous and sturdy plant. The present application provides robust tomato hybrids, homozygous for the dg mutation, devoid of the undesirable pleiotropic traits associated with this mutation as disclosed in the citation that follows (spec. of WO 2005/072515):

"Within the scope of the present invention the term hybrid varieties encompasses any robust hybrid variety that is homozygous for the dg mutation devoid of the traits poor germination rate, shallow root system, brittle stems, thin and/or fragile leaves, premature defoliation, low yield and small fruit."

p. 4, l. 13-16

The present application further defines the claimed tomato hybrids as **vigor, hardy and adapted for growth on a commercial scale**, as demonstrated in the following citations:

"The F1 hybrid varieties of the present invention are superior over the parent lines in their plant vigor and adaptation for growth in a commercial scale, including field resistance to various diseases and better yield."

p. 4, l.21-23

"The novel varieties of the present invention including parental lines or hybrids adapted for commercial cultivation produce commercial scale crop yields, in which the average lycopene content is at least 200 ppm."

p. 5, l. 23-26

"Step 5: Further selection was performed by the following sequential steps:

a) Each breeding line was examined for average performance, including: lycopene content, volume of root system, vigor, fruit size and fruit yield, leaf

appearance and health and total soluble solid content (TSS/BRIX). Breeding lines showing the highest results were selected for further analysis."

p. 11, l. 7-12

"Plant quality, scored according to the followings: vigor, plant resistance to various diseases, plant resistant to stress, foliage health and density, unity of ripening and fruit quality at ripening."

p. 12, l. 4-6

"The present invention relates to hardy tomato varieties, producing high lycopene fruit for the fresh fruit market as well as for the tomato processing industry. Specifically, the present invention relates to hardy tomato varieties homozygous for the dg mutation, producing fruit comprising an average lycopene content of at least two fold its content in currently available commercial varieties, while devoid of undesirable traits hitherto linked to the dg mutation."

p. 3, l. 20-29

"The present invention now discloses novel, hardy hybrid tomato varieties which are dg homozygous, comprising a very high lycopene content while being devoid of the undesired pleiotropic effects associated with the dg mutation."

p. 8, l. 31-32; p. 9, l. 1-2

Thus, the definition of the term "robust" and terms cited in claim 1 are well known in the conventional relevant art.

2. "deleterious traits"

With respect to the term deleterious traits, it is the Applicant's view that this term is an acceptable term that is **commonly understood by tomato breeders** (one skilled in the art) in the field, without necessarily defining it quantitatively. The pleiotropic deleterious traits known to be linked with the *dg* mutation and listed in claim 5 of the present application, namely poor germination rate, shallow root system, brittle stems, thin and/or fragile leaves, premature defoliation, low yield, and small fruit are understood by persons in the art **without necessarily having them defined quantitatively**. In other words, any tomato breeder knows what is meant by these terms *per se* as applied to attempts to breed commercial plant varieties. In fact, the Applicant attaches to this document, official guidelines administered by the Ministry of Agriculture of the State of Israel that are directed to breeders of tomato crop varieties (Appendix I).

These guidelines provide the breeders with parameters to qualitatively estimate tomato varieties. The tomato varieties tests encompass **visual evaluation** of parameters such as endogenous color, presence of veins, jelly, hollowness, "shoulder", vegetative growth, leaf cover of the fruit, disease resistance, fruit shape, general color, hardness/ solidness of the fruit, healthiness of the plant and pulp/flesh color. It should be emphasized that these parameters are **visually evaluated in the field** by tomato breeders and they are **qualitatively scored by a relative scale** (i.e. poor, high, soft, weak, few, many, solid, good and medium) as presented in the Table 2 of Appendix I. The subsequent conclusion of considering all these visual estimations is a general evaluation with respect to the determination if the crop yield of the specific variety is suitable for **commercial use**. Thus in view of the above it can be concluded that the terms listed in claim 5 are acceptable as objective parameters for determining plant quality and adaptation of a field crop such as tomato for growth on a commercial scale (Appendix I). The high lycopene tomato varieties of the present application, exemplified by hybrid HA3518, are devoid of the deleterious traits listed in claim 5 and as a result perform a high crop yield (between about 9 kg/m² and 12.7 kg/m²), and comprise fruits with high Brix value of about 4.5 (Examples 1 and 2).

Applicant further provides an expert Declaration under 37 CFR 1.132 of Peleg that supports the data and arguments detailed above (see Appendix II). In the Declaration under 37 CFR 1.132 it is stated by an experienced tomato breeder that the term "deleterious traits" cited in claim 1 is used in the respective art (i.e. Cornelius S. B et al., PANS, 2006, see p.7927-7928; Sacks E.K. and Francis, D.M. 2001. J. Amer. Hort. Sci. 126(2):221-226, see p. 222; Jarret RL et al., J. Amer Soc. Hort. Sci 109: 873-878; Thompson AE 1961 Proc. Amer. Soc. Hort.Sci 78: 464-473) and is understood by persons in the art without necessarily having them defined quantitatively. It is further stated that the *dg* associated deleterious traits such as brittle stems, fragile leaves and small fruit claimed in claim 5, are conventional terms used by ordinary tomato breeders to describe plant quality and presence of undesirable effects.

In view of the above, Applicant respectfully submitted that the term "deleterious traits" is a well understood term and particularly pointed out in the specification. Thus, one skilled in the art would understand the metes and bounds which Applicant regards as the invention.

3. "average content in currently available varieties "

Applicant has deleted this phrase from the claims and replaced it with the phrase "value of lycopene content" as cited in claim 4, within the fruits of the homozygous *dg* hybrid tomato varieties claimed in claim 1. Claim 4 has been canceled. Thus, amended claim 1, now states that the lycopene content concentration as follows:

*"A robust, hardy, vigorous tomato variety adapted for growth on a commercial scale, homozygous for the *dg* mutation, wherein tomatoes grown from this variety have an average lycopene content of at least 200 ppm plus or minus the standard error from the mean, while being devoid of deleterious traits associated with the *dg* mutation, when measured at peak lycopene content."*

In view of the above amendments and arguments, Applicant respectfully requests that this rejection be withdrawn.

35 U.S.C. § 112, first paragraph Rejections

Claims 6, 7, 13, 14, 26 27, 33 and 34 were rejected by the Examiner as failing to comply with the written description requirement under 35 U.S.C. § 112, first paragraph, for the reasons set forth on pages 5-7 allegedly being unclear whether a deposit of seeds claimed in the present application has been made.

Applicant respectfully points out that a deposit under the terms of the Budapest Treaty has been made. The Applicant has deposited with the ATCC 2500 seeds of tomato hybrid designated HA3518 (Accession No. PTA-5796), on January 29, 2004. Complying with the Examiner's demand, the Applicant provides herewith documents verifying said deposit as well as a Declaration by the Applicant that the seeds were deposited under the Budapest Treaty terms (Appendix III).

Furthermore, claims 6, 13 and 33 have been canceled.

Claims 1-5, 8-12, 15-25, 28-32 and 35-38 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification, while being enabling for deposited variety HA3518, does not reasonably provide enablement for any tomato plant in scope with the claims. Applicant respectfully traverses and asserts that the present application meets the enablement requirements for the following reasoning:

First, Applicant has now narrowed the scope of claim 1 to a "**robust, hardy, vigorous tomato variety adapted for growth on a commercial scale**", characterized by homozygosity for the dg mutation, "*wherein tomatoes grown from this variety have an average lycopene content **of at least 200 ppm plus or minus the standard error from the mean**, while being devoid of deleterious traits associated with the dg mutation, when measured at peak lycopene content.*"

The specific lycopene content cited in amended claim 1 is disclosed and demonstrated in the application (i.e. Example 1). In the specification of the filed application Hybrid strain HA3518 is provided as a **working example** of the claimed tomato variety which is homozygous for the dg mutation, and having fruits with an average lycopene content of at least 200 ppm while being devoid of deleterious traits associated with the dg mutation. This example provides ample evidence that the Applicant is **able to produce** and **was in possession** of the claimed tomato

variety having the novel combination of the claimed characteristics as claimed in amended claim 1, at the time of filing. The example of hybrid HA3518 was produced with the exact detailed crossings, screening and selection procedures, disclosed and enabled in the application (steps 1 to 5 of the description and Examples 1-3, Figs 1 and 2) and resulted in tomato variety with the claimed characteristics of homozygosity for the dg mutation, average lycopene content of at least 200, while being devoid of deleterious traits associated with the dg mutation (Table 3, Figs 1 and 2). The following citations provide support for the above arguments:

"Hybrid HA3518 serves as an example for the teaching of the present invention, and representatives of its seeds have been deposited with the ATCC on Jan. 29, 2004."

p. 6, l. 25-27

"According to one currently preferred embodiment, the present invention provides tomato hybrid seeds designated HA3518. Hybrid HA3518, representative seeds of which have been deposited with the ATCC on Jan. 29, 2004 (Accession number not available) serves as an example for the hybrids of the present invention, wherein the plants grown from the seeds are homozygous for the dg mutation, produce fruit crop yield comprising an average lycopene content of at least two fold its content in currently available crop yields, and is devoid of the dig associated undesired pleiotropic traits."

p. 12, l. 23-29

More specifically, the specification of the filed application details the exact cross used for the production of the stable parent lines of the present invention, as cited below:

"The stable parent lines of the present invention were developed from a cross between plants carrying the dg mutation (the dg mutant of L. esculentum cv Manapal) and a mixture of germplasm from proprietary and valuable breeding

material belonging to Hazera Genetics Ltd., the applicant of the present invention."

Thus, the well characterized homozygous dg mutant Manapal, which encompass all pleiotropic deleterious traits associated with the dg mutation (Sacks E.K. and Francis, D.M. 2001. J. Amer. Hort. Sci. 126(2):221-226; Report of the tomato genetics cooperative, vol.58, September 2008, see Table 3) is used as a first parent line. In order to obtain the claimed plant devoid of the undesirable deleterious traits, the mentioned above mutant was crossed with a commercial tomato plant possessing mixture of germplasm comprising advanced commercial breeding material. Examples of such a plant include Hypeel 287 or Asgro F2.

In fact, these plants used in the cross to obtain the plant having the claimed characteristics are now claimed in amended claims 28 and 32.

In addition, Example 1 of the present application enables and teaches a person skilled in the art how to produce the tomato varieties with the claimed characteristics, including teaching how and which plants to select. More specifically, Example 1 details specific steps, for production of a tomato variety with the claimed characteristics, exemplified by HA3518 hybrid:

"Seedlings obtained according to steps 1 to 5 described herein above served as a source for the production of the HA3518 hybrid.

Lines stabilized for the dg mutation were selected as parent lines The presence of the dg mutation was verified by PCR reaction using a dg-probe, and by the phenotypic effects of the mutation.

This parent plants showed normal growth pattern with a developed roots system and healthy leaves, and produced fruit containing lycopene content over 200 ppm.

300 F1 hybrids were produced using these lines and other commercial valuable material. Eight hybrids were found to contain high lycopene content (over 200 ppm), and normal growth pattern. The parent lines of these 8 selected

hybrids were self pollinated and planted for sufficient number of generations to obtain stabilized parent plant, homozygous for the dg mutation while devoid of: poor germination rate; shallow root system; brittle stems; thin and/or fragile leaves; small fruit; low crop yield. The eight hybrids were then produced again using the stable parent lines, hybrid HA3518 serving as a representative example.

The stable parent from which this HA3518 hybrid was produced were further self-pollinated and selected for best-performing plants in terms of horticulture measures. The new stabilized parents were used to produce a second generation of hybrid HA3518, representative seeds of which have been deposited with the ATCC on Jan. 29, 2004.

In the above citation the traits and parameters used to select the tomato plants with the claimed characteristics are defined, and as extensively explained above these traits are acceptable in the relevant literature to be used for the aforementioned purpose of testing tomato varieties for absence of deleterious traits and adaption for growth on commercial scale.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann*

Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

It is important to note, the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. Again, the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement).

Based on the above arguments, amendments to the claims and citations Applicant respectfully submits that the present specification provides sufficient guidance and tools to enable one skilled in the art of plant breeding, *not only* to produce the specific deposited HA3518 hybrid, but to further produce other tomato varieties having the claimed dg homozygosity, fruits having lycopene content of at least 200 ppm and absence of deleterious traits associated with the dg mutation (i.e. HA3512, HA3513 of Table 3), without undue experimentation.

The disclosure of the present application provides a person skilled in the art of plant breeding sufficient teaching to make and/or use the invention, namely the crossings, selection and screening steps performed to reach the claimed tomato variety adapted for growth on a commercial scale homozygous for the dg mutation, devoid of the deleterious traits linked to the mutation, as cited below:

"The development of a commercial, superior tomato variety requires a significant breeding effort, especially what was required to break the linkage between the dg locus and the associated deleterious genes."

p. 9 l. 3-5

The claims are now specifically directed to a robust, hardy, vigorous tomato variety adapted for growth on a commercial scale, having the properties set forth in amended claim 1. Applicant fully describes the varieties in the specification and provides working examples, including biological seed deposit.

While some routine task and breeding are always required in producing any new variety, the present application provides sufficient direction and examples such that no undue experimentation would be required by a tomato breeder (one skilled in the art). Furthermore, with the tools, teachings and working examples provided by the Applicant, one skilled in the art of plant breeding would have a reasonable expectation of success of producing the claimed tomato varieties.

Therefore it is respectfully submitted that, in view of the above, claims 1-5, 8-12, 15-25, 28-32 and 35-38 as amended comply with the enablement requirement under 35 U.S.C. § 112, first paragraph.

Claims 1-5, 8-12, 15-25, 28-32 and 35-38 were rejected under 35 U.S.C. § 112, first paragraph, for failure to meet the written description requirement for the reasons set for on pages 8-10 of the Office Action.

Applicant respectfully traverses this rejection and points out that hybrid HA3518 is a representative example of the genus of tomato varieties claimed. The Applicant shows possession by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the presently claimed invention (*Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997)). The claims are now specifically directed to a robust, hardy, vigorous tomato variety adapted for growth on a commercial scale, homozygous for the dg mutation, wherein tomatoes grown from this variety have an average lycopene content of at least 200 ppm plus or minus the standard error from the mean, while being devoid of deleterious traits associated with the dg mutation, when measured at peak lycopene content. In the specification of the filed application, hybrid HA3518 is provided as a working example of the claimed tomato variety (Example 1). This example provides ample evidence that the Applicant is able to produce

and was in possession of the claimed tomato variety having novel combination of the claimed characteristics, as claimed in amended claim 1, at the time of filing.

The example of hybrid HA3518 was produced with the exact detailed crossings, screening and selection procedures disclosed and enabled in the application (steps 1 to 5 and Examples 1-3), and resulted in the tomato variety with the claimed characteristics, exemplified by hybrid HA3518. The following citations support the above arguments:

"The stable parent lines of the present invention were developed from a cross between plants carrying the dg mutation (the dg mutant of L. esculentum cv Manapal) and a mixture of germplasm from proprietary and valuable breeding material belonging to Hazera Genetics Ltd., the applicant of the present invention."

"The resulting progeny from this cross are then crossed again to the recurrent parent and the process is repeated until a tomato plant is obtained wherein essentially all of the desired morphological and physiological characteristics of the recurrent parent are recovered in the converted plant, in addition to the single transferred gene from the nonrecurrent parent. Backcrossing methods can be used with the present invention to improve or introduce a characteristic into the parent lines."

"Pollen and ovules from these tomato plants; the seeds produced from same and the plants grown from the seeds; plants regenerated from tissue cultures regenerated from the plants of the present invention; and plants or parts thereof having all of the physiological and morphological characteristics of the tomato plants of the present invention are also encompassed within the scope of the present invention."

"Hybrid HA3518, seeds of which have been deposited with the ATCC on Jan. 29, 2004 serve as an example for the teaching of the present invention."

"Hybrid HA3518, representative seeds of which have been deposited with the ATCC on Jan. 29, 2004 (Accession number not available) serves as an example for the hybrids of the present invention, wherein the plants grown from the seeds are homozygous for the dg mutation, produce fruit crop yield comprising an average lycopene content of at least two fold its content in currently available crop yields, and is devoid of the dg associated undesired pleiotropic traits."

In addition, the disclosure of the present application provides further characteristics of hybrid HA3518 such as fruit yield, Brix and pH (Example 2. Table 3) and compares it with available commercial varieties (Fig. 2). These characteristics are claimed in new claims 39- 41.

With respect to claims 15-27, 29, 30-31 and 36-38 drawn to F1 and F2 progenies of hybrid HA3518, it is submitted that the claimed F1 and F2 plants are identified by the all the characteristics of HA3518 as explicitly detailed in the citations of the specification below:

"Pollen and ovules from these tomato plants; the seeds produced from same and the plants grown from the seeds; plants regenerated from tissue cultures regenerated from the plants of the present invention; and plants or parts thereof having all of the physiological and morphological characteristics of the tomato plants of the present invention are also encompassed within the scope of the present invention."

P. 51. 8-12

"The present invention also relates to seeds harvested on the F1 hybrid tomato plants and plants grown from these seeds. A common practice in plant breeding is using the method of backcrossing to develop new varieties by single trait conversion. The term single trait conversion as used herein refers to the incorporation of new single gene into a parent line wherein essentially all of the

desired morphological and physiological characteristics of the parent lines are recovered in addition to the single gene transferred."

p. 13 l. 14-20

*"The resulting progeny from this cross are then crossed again to the recurrent parent and the process is repeated until a tomato plant is obtained **wherein essentially all of the desired morphological and physiological characteristics of the recurrent parent are recovered in the converted plant**, in addition to the single transferred gene from the nonrecurrent parent. Backcrossing methods can be used with the present invention to improve or introduce a characteristic into the parent lines"*

p. 13, l. 29-33; p. 14 l. 1-2

*"Once the parent lines that give the best hybrid performance have been identified, the hybrid seed can be produced indefinitely, **as long as the homogeneity and the homozygosity of the parents is maintained.**"*

p. 9 l. 24-26

Furthermore, the claims now require progenies of hybrid HA3518 to retain all the morphological and physiological characteristics of the hybrid parent HA3518, as claimed in amended claims 15, 26, 27, 29, 30 and 37.

In view of the claim amendments, examples, biological seed deposits and detailed disclosure providing all of the claimed variety characteristics, one skilled in the art would reasonably believe that Applicant was in possession of the invention as presently claimed at the time of filing. Applicant therefore respectfully requests that this rejection be withdrawn.

In addition, the single gene conversion set forth in presently pending claim 37 is explicitly disclosed in the specification and the plant comprising a transformed gene preserves all the morphological and physiological characteristics of the parent lines, as outlined below. Claim 37 has been amended accordingly.

"The term single trait conversion as used herein refers to the incorporation of new single gene into a parent line wherein essentially all of the desired morphological and physiological characteristics of the parent lines are recovered in addition to the single gene transferred."

p. 13 l.16-20

"The resulting progeny from this cross are then crossed again to the recurrent parent and the process is repeated until a tomato plant is obtained wherein essentially all of the desired morphological and physiological characteristics of the recurrent parent are recovered in the converted plant, in addition to the single transferred gene from the nonrecurrent parent."

p. 13 l. 29-33

The transformed gene is defined as selected from a group consisting of "herbicide resistance, insect resistance, resistance to bacterial, fungal or viral disease and male sterility as claimed in amended claim 39 and disclosed in the specification:

"According to one embodiment, the transformed gene or genes confer a characteristic selected from the group consisting of herbicide resistance, insect resistance, resistance to bacterial, fungal or viral disease, male sterility and improved nutritional value."

p. 7 l. 28-31

Thus, it respectfully requested that presently pending claim 37 be allowed as well.

35 U.S.C. § 102 and 103 Rejections

Claims 1-5, 8-12, 15-17, 24-25, 28-32, 36 and 37 were rejected under 35 U.S.C. § 102(e) or alternatively under 35 U.S.C. § 103(a) as obvious over Levin et al. Claims 31 and 36-38 were rejected under 35 U.S.C. § 102(b). Claims 1-5, 8-12, 15-25, 28-32 and 36-38 were alternatively

rejected under 35 U.S.C. § 103(a) as obvious over Levin et al. in view of Hoogstraten. Applicant respectfully traverses.

Applicant submits herewith amended claims that are directed to a robust, hardy, vigorous tomato variety adapted for growth on a commercial scale. The tomato variety is characterized by homozygosity for the dg mutation, lycopene content of at least 200 ppm, and absence of deleterious traits associated with the dg mutation.

It is respectfully submitted that a tomato variety possessing this combination of characteristics is novel and nonobvious over the prior art. The absence of deleterious traits associated with the dg mutation is verified by the high yield of the variety claimed in the present invention (Figs. 1 and 2):

"The average crop yield of hybrid HA3518 was 10.8 Kg/m², which is considered as average to high yield for a commercial variety."

p. 17 l. 4-5

Furthermore, Applicant attaches to this document experimental data showing the superiority of the claimed tomato variety over the homozygous dg mutant LRT 915 of Levin et al. (WO 03/057917) (Appendix IV).

Levin's et al. disclosure is directed to the characterization of the dg mutation and provides means and methods for detecting said mutation. The disclosure of Levin et al. does not provide homozygous dg mutant plants which are adapted for growth on a commercial scale and/or comprise fruit yield of at least 9 kg/m². Levin et al. does not teach or suggest products with a break of the known linkage between the dg mutation and the undesired pleiotropic traits which include low yield, poor germination rate, brittle stems, fragile leaves, small fruits, shallow root system and premature defoliation, nor does Levin teach or suggest methods for achieving this breakage. Applicant was the first to disclose and enable these features and characteristics.

The experimental data showing that Levin's tomato mutants are pleiotropic is provided herewith (Appendix IV). In these experiments, performed on 2002 by the Applicant, a comparison of various pleiotropic traits associated with the dg mutation, of LRT915 of Levin et

al. (Table 1 of Appendix IV) and the deposited hybrid HA3518 of the present application, was made. Based on repeated observations, it was found that LRT915 is pleiotropic with respect to the following traits and/or phenotypes: appearance of sensitive and fragile leaves, sudden leaf death, brittle stems, poor root system, two weeks earlier rotting fruits and lower seed germination rate (Table 1 of Appendix IV). In addition, a comparison of fruit yield and lycopene content of LRT915 and HA3518 was performed at several distinct locations and environmental conditions in Israel. The results presented conclusively show that HA3518, which is an example of the tomato varieties claimed in the currently submitted claim 1, is superior in higher yield and higher lycopene relative to the cited strain of Levin (LRT915) (Appendix IV). Furthermore, the lycopene concentration of the LRT915 tomato fruits in all locations examined was lower than 200 ppm, while the average HA3518 lycopene concentration is higher than 200 ppm, as claimed in the currently submitted claim 1.

Thus, HA3518, the exemplary variety of the invention has a proven high yield, high germination rate, good fruit quality, strong root system, strong foliage, and fruits that rot at least two weeks later than LRT915. The Applicant wishes to stress that HA3518 does not suffer from the attendant pleiotropic effects found in the high lycopene prior art LRT915, and this is because the invention of the present application is the breakage of the link between dg and the pleiotropic traits.

In view of the above experimental data and arguments, it is respectfully submitted that the present application is novel and inventive over the cited WO 03/057917 document (Levin). It is also submitted that the currently amended claims are novel and inventive over Hoogstraten as well. Neither Levin nor Hoogstraten, alone or in combination, teach or suggest the presently claimed invention e.g., a tomato variety, wherein the plants are homozygous for the dg mutation and retains all of the physiological and morphological characteristics of the deposited HA3518 line (claims 15, 26, 27, 29, 30 and 38)

Therefore, for all the above reasons, the Applicant respectfully requests that the rejections under 35 U.S.C. §§ 102 and 103 be withdrawn and the claims as presently pending be allowed.

CONCLUSION

In response to the outstanding Notice of Non-Compliant Amendment, Applicant has removed all references to WO 2005/072515 in the amendments to the specification. In addition and to avoid confusion, the word "Abstract" has been removed from the first page of Appendix I. Applicant believes that this addresses the Examiner's concerns.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested. If the Examiner has any remaining questions or concerns, please contact Applicant's representative at (602) 916-5404 to expedite the allowance of the application.

Respectfully submitted,

September 12, 2011
Date

/Rodney J. Fuller/
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602-916-5404

APPENDIX I

**Tests for commercial tomato varieties administered by the Ministry of
Agriculture of the State of Israel**

The attached document describes official guidelines administered by the Ministry of Agriculture of the State of Israel that are directed to breeders of tomato crop varieties. These guidelines provide the breeders with parameters to qualitatively evaluate tomato varieties. The tomato varieties test encompass visual evaluation of parameters such as endogenous color, presence of veins, jelly, hollowness, "shoulders" color, vegetative growth, fruit leaf cover, disease resistance, fruit shape, general color, hardness/ solidness of the fruit, healthiness of the plant and pulp/flesh color. It should be emphasised that these parameters are visually evaluated in the field by tomato breeders and they are qualitatively scored by a relative scale (i.e. poor, high, soft, weak, few, many, solid, good, pronounced and medium) as presented in Table 2 of the attached document. The subsequent conclusion of considering all these visual evaluations is a general evaluation with respect to the determination if the crop yield of the specific variety is suitable for commercial use.

Tests for Commercial Tomato varieties (2002)

Table 1: Tomato varieties' tests by location

Location	Test	No. of varieties	No. of repeats	Seeding date	Harvest date
Eden farm	Regular varieties *	6	6	20.2.02	18.6.02
Eden farm	Special varieties	8	6	20.2.02	16.6.02
Eden farm	Introduction/ Acclimatization	8	2	20.2.02	16.6.02
Yavne'el	Regular varieties	6	4	16.3.02	8.7.02
Acre	Regular varieties 1	17	2	12.4.02	31.7.02
Acre	Regular varieties 2	17	4	12.4.02	7.8.02
Acre	Regular varieties 3	17	3	12.4.02	14.8.02
Acre	Special varieties 1	17	1	12.4.02	31.7.02
Acre	Special varieties 2	19	2	12.4.02	12.8.02
Acre	Introduction/ Acclimatization	10	4	12.4.02	8.8.02
Mevo-Hamah	Regular varieties	13	6	12.5.02	2.9.02
Mevo-Hamah	Special varieties	13	6	12.5.02	30.8.02
Mevo-Hamah	Introduction/ Acclimatization	24	2	12.5.02	2.9.02

* = Harvest by a combine harvester

Quantitative and qualitative parameters for variety comparison:

The parameters for testing the varieties were evaluated in the field and in the laboratory for field crops in the Agricultural Faculty of the State of Israel (by Tehila Bloch):

In the field: red yield, green yield, single fruit weight, % of spines

In the laboratory- evaluation of veins quantity, gel, hollowness, "shoulders", color (visual evaluation), pH, Brix, Brix yield (red yield multiplied by Brix %)

Varieties evaluation- Additional parameters for varieties evaluation in the field are visual parameters tested by skilled persons in the field. These parameters include vegetative growth, fruit leaf cover, healthiness of the plant, fruit shape, fruit color, fruit solidness, and general weighted evaluation performed by the following formula:

15% vegetative growth score + 15% fruit leaf cover score + 30% color score + 40% solidness score

The visual evaluation, performed in the field and in the laboratory, is relatively scored between 1 and 5, as demonstrated in Table 2 that follows:

Table 2: Variety's traits evaluation score

Trait	1	2	3	4	5	6
Endogenous color	pink		red		dark red	
veins	many		few		absent	
Jelly	green	red				
hollowness	pronounced		poor		absent	
"shoulders"	green/ white		yellow		red	
growth	poor		moderate		good	
leaf cover	poor		moderate		good	
disease resistance	good		moderate		healthy	
Fruit shape	round		blocky		elongated	"pear" like
General color	faint		moderate		good	
solidness	soft		moderate		solid	
General estimation *	rejected		average quality		excellent	

Results

The results are summarized according to the location of the tests and according to the deferent tests performed.

In the field tests- The varieties are ordered according to the general evaluation score.

In Acre, several subsequent harvests of regular and special varieties were performed, for yield comparison in different dates, for early/ late variety, and for field adaptation.

The statistical tests were performed by Yael Phuzin by SAS software, using S.N.K test with significance value of 0.05.

APPENDIX II

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ezri Peleg et al.
Application No.: 10/587,789
Attorney Docket No.: 27275.005
Filing Date: March 03, 2008
Title: HIGH LYCOPENE TOMATO
VARIETIES AND USE THEREOF

Examiner: Phuong T. Bui
Group Art Unit: 1638

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

Dear Examiner,

In order to assist in the prosecution of this application and the traversal of the claims rejection subjected by the Examiner, I, Ezri Peleg, do hereby declare as follows.

BACKGROUND

My name is Ezri Peleg. I am a plant breeder in the Research & Development Division of Hazera Genetics Ltd. Mivhor, M.P Lachish Darom 79354 Israel. I received my M.sc. degree at the Hebrew University in Rehovot, Israel, on 1996.

My research interests and field of expertise are tomato breeding and phytopatology and crop protection.

PROFESSIONAL OPINION

It is in my capacity as a plant breeder and a researcher in these fields that I offer the following comments and experimental data in the light of my reading of US patent application 10/587,789, (hereinafter referred to as the **present application**), the Office Action of March 07, 2011, the Response to the Office Action, including the set of amended claims attached to this letter and the publication of Levin et al WO 03/057917 A2 cited by the Examiner.

The present application claims robust, hardy, vigorous tomato varieties adapted for growth on a commercial scale, homozygous for the *dg* mutation, producing fruit crop yield comprising an average lycopene content of at least 200 ppm, wherein the plants are devoid of the *dg* linked deleterious traits (amended claim 1). Tomato plants carrying the *dg* mutation are characterized by their dark-green fruits, which, upon ripening, become dark red, due to high lycopene content. However, the *dg* mutation is known to be linked with deleterious pleiotropic traits which prevented the use of the high pigment *dg* gene in breeding programs (Sacks E.K. and Francis, D.M. 2001. J. Amer. Hort. Sci. 126(2):221-226). It is emphasised that the term "deleterious traits" cited in claim 1, covered by the traits listed in claim 5 of the present application, namely poor germination rate, shallow root system, brittle stems, thin and/or fragile leaves, premature defoliation, low yield, and small fruit are acceptable terms which are commonly understood by tomato breeders in the field. Furthermore, these terms are understood by persons in the art without necessarily having them defined quantitatively. In other words, any tomato breeder knows what is meant by these terms *per se* as applied to attempts to breed commercial plant varieties.

The surprising and unexpected achievement of the present invention is that the tomato varieties of the present application, while homozygous for the *dg* mutation, *do not* show any of the pleiotropic and deleterious effects linked to the *dg* mutation. This is extensively claimed, disclosed and demonstrated in the application. In addition to the high lycopene concentration of the fruits, which is at least 200 ppm (amended claim 1 and Example 1), the tomato varieties of the present invention are devoid of the *dg*-linked deleterious traits, as specifically claimed in the originally filed claims 1 and 5.

The term "deleterious traits" cited in claim 1, and the traits defined in the originally filed claim 5 and in the Description section of the application, are commonly used in

the respective art (i.e. Cornelius S. B et al., PANS, 2006, see p.7927-7928; Sacks E.K. and Francis, D.M. 2001. J. Amer. Hort. Sci. 126(2):221-226, see p. 222; Jarret RL et al, J. Amer Soc. Hort. Sci 109: 873-878; Thompson AE 1961 Proc. Amer. Soc. Hort. Sci 78: 464-473) thus allow one skilled in the art to objectively determine deleterious traits. *dg* associated deleterious traits such as brittle stems, fragile leaves and small fruit claimed in claim 5, are conventional terms used by ordinary tomato breeders to describe plant quality and presence of undesirable effects. Examples 1 and 2 of the specification clearly show that the novel high lycopene hybrids of the present application are superior over commercially available varieties examined in production of fruits with significantly higher Total Soluble Solids (Brix), lycopene content, plant quality, fruit size, fruit yield, leaf appearance, and have crop yield which is considered as average to high, relative to a commercial variety (Figs 1, 2 and Tables 2 and 3). The present application defines the average crop yield of the claimed tomato hybrid varieties, (exemplified by hybrid HA3518) as at least 9 Kg/m² (Example 1). The average Brix value of the tomato hybrid varieties of the present invention is defined and exemplified as about 4.5 (Example 2). These values are further defined in the new submitted claims 39-41. Such high yield beneficial traits are a consequence of the absence of the pleiotropic deleterious effects commonly described to be linked to the *dg* mutation (Sacks E.K. and Francis, D.M. 2001. J. Amer. Hort. Sci. 126(2):221-226). Fig. 1 of the present application clearly shows the phenotypic difference between a tomato plant homozygous for the *dg* mutation, which retains the deleterious pleiotropic effects associated with the mutation (A) or is devoid of such effects (B). The apparent difference is sharp and therefore is distinguishable by any person skilled in the art, especially a tomato breeder. Thus the deleterious traits listed in claim 5 can be determined by any person skilled in the relevant art.

In other words, the present invention has successfully provided, as claimed in the currently submitted claim 1, robust, hardy, vigorous tomato varieties adapted for growth on a commercial scale, homozygous for the *dg* mutation, wherein tomatoes grown from these varieties have an average lycopene content of at least 200 ppm, while being devoid of deleterious traits associated with the *dg* mutation, when measured at peak lycopene content.

As further evidence for the common usage and meaning of the deleterious traits defined by the terms listed in claim 5, a document describing official guidelines administered by the Ministry of Agriculture of the State of Israel, directed to breeders of tomato crop varieties, is attached (Appendix I). These guidelines provide the breeders with qualitative parameters, tested in the field, to evaluate the suitability of tomato varieties for commercial use. The tomato varieties tests encompass visual evaluation of parameters such as endogenous fruit color, presence of veins, jelly, hollowness, "shoulders", vegetative growth, fruit leaf cover, disease resistance, fruit shape, general color, hardness/ solidness of the fruit, healthiness of the plant and pulp/flesh color. It should be emphasised that these parameters are visually evaluated in the field by tomato breeders and they are qualitatively scored by a relative scale (i.e. poor, high, soft, weak, few, many, solid, good, pronounced and medium) as presented in Table 2 of the attached document (Appendix I). The subsequent conclusion of considering all these visual estimations is a general evaluation with respect to the determination if the crop yield of the specific variety is suitable for commercial use.

Thus traits as cited in claims 1 and 5 of the present application are acceptable terms in the field of tomato breeding and their common usage and meaning is understood *per se* by any person skilled in the relevant art.

Verification

I further declare that all statements made herein of my knowledge are true and all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon

Signed: 

Date: May 29, 2011

APPENDIX III



Wednesday, January 28, 2004

To: American Type Culture Collection
Attn: Patent Depository
10801 University Blvd
Manassas, VA 22010-2209
(703) 365-2700

Declaration

Seeds for Patent Deposit and Storage HA3518 - Hazera Genetics Ltd.

Package content 2500 Tomato seeds
(in 100 labeled packets of 25 seeds each - total of 25 gram)

Proforma # HG280104

Kind of seeds Lycopodium esculentum

Variety Tomato hybrid seeds designated HA3518

Origin of seeds Israel

The Use of seeds For patent deposit purposes to be kept in storage

Sincerely,

Dr. Shoshan Haran

Shoshan Haran
Scientific and Business Manager
Hazera Genetics
Brurim MP Shikmim
Israel 79837

More than **60** Years of Innovation

Hazera Genetics Ltd. Headquarters
M.P. Shikmim 79837 Israel, Tel+972-8-8508850, FAX+972-8-8502442, Email: HAG@hazera.com, WWW.hazera.co.il





Wednesday, January 28, 2004

To: American Type Culture Collection
Attn: Patent Depository
10801 University Blvd
Manassas, VA 22010-2209
(703-365-7700)

Attn:
Marie Harris
ATCC Patent Department

Re: Seeds for deposit for patent purpose - Tomato Hybrid HA3518
Hazera Genetics Ltd.

Dear Marie Harris:

Please find enclosed 2500 tomato seeds of *Lycopersicon esculentum* for patent deposit purposes - to be kept in storage.

Variety - Tomato hybrid seeds designated HA3518
Company - Hazera Genetics Ltd.

Please also find attached:

1. The Budapest Treaty Deposit Form
2. Declaration accompanying the seeds
3. A Phyto-Sanitary form # IL-11238-04
4. The sum of 2,500\$ was transferred via the First International Bank of Israel to Account Number 003933990352, ABA # 052001613, American Type Culture Collection, c/o Bank of America, N.A., Baltimore, MD. Federal ID #53-0196548

Please confirm receipt of the seeds to me at: Fax: 972-8-8600560 or E-mail: shoshan@hazera.com

Sincerely,

Shoshan Haran

Dr. Shoshan Haran
Scientific and Business Manager
Hazera Genetics
Brurim MP Shikmim, Israel 79837

More than **60** Years of Innovation

Hazera Genetics Ltd. Headquarters
M.P. Shikmim 79837 Israel, Tel: +972-8-8508850, FAX: +972-8-8602442, Email: HAG@hazera.com, WWW.hazera.co.il



ATCC

10801 University Blvd • Manassas, VA 20108-2209 • Telephone: 703-365-2760 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Hazera Genetics Ltd.
Attn: Dr. Eyal Vardi
R&D Division
Mivtar, M.P. Lachish Daron
70134 Israel

Deposited on Behalf of: Hazera Genetics Ltd.

Identification Reference by Depositor:

Patent Deposit Designation

Lycopersicon esculentum: HA 3538

PIA-5796

The seeds were accompanied by a scientific description, a proposed taxonomic description indicated above. The seeds were received February 5, 2004 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the seeds for 30 years.

The seeds will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the seeds and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said seeds.

If the seeds should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with viable seeds of the same.

The seeds will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the seeds cited above was tested February 17, 2004. On that date, the seeds were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20108-2209 USA

Signature of person having authority to represent ATCC:

Marie Harris
Marie Harris, Patent Specialist, ATCC Patent Depository

Date: February 27, 2004

cc: Dr. Hedva Schickler

Ref: Docket of Case No.: HZR/001 PGT



BUDAPEST TREATY DEPOSIT FORM (BP/1)

American Type Culture Collection

P.O. Box 1549
Manassas, VA 20108

TO DEPOSIT OR TO CONVERT A DEPOSIT TO MEET THE REQUIREMENTS OF THE BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF A PATENT PROCEDURE

ALL QUESTIONS MUST BE COMPLETED IN ENGLISH. PLEASE USE ONE FORM FOR EACH STRAIN DEPOSITED

1. Name of deposit: Please mark the appropriate box and provide the information requested for the material:

- ☐ Microorganism: the complete scientific name including genus and species plus the source of the material.
☐ Virus: the name, whether plant or animal, and source including geographic location.
☐ Cell line: the species and tissue of origin, geographical source of isolation, and any known associated hazards (HIV, EBV, etc.).
☐ Genetic material: the name of organism from which vector, clone or library is derived, the source of the DNA insert identified by species (e.g., human, mouse) or scientific name, the name of gene, and the identity of the host organism.
☐ Consortium or mixed culture: the identity of each component of the mixture.
Seeds, embryos, insect eggs, etc.: the common name, the scientific name of the source of the deposit, and geographical source.

Information: TOMATO (Lycopersicon esculentum) B. 22

2. Strain designation (i.e., number, symbols, etc.) (15, 3618)

The strain designation must correspond with the vial labels.

3. Is this an original deposit under the Budapest Treaty? ☒ Yes ☐ No

4. Is this a request for a conversion of a deposit already at the ATCC to take the requirements of the Budapest Treaty?

☒ Yes ☐ No

If yes, please indicate ATCC designation:

5. Is this deposit a mixture of microorganisms or cells? ☐ Yes ☒ No

If yes, please describe:

Provide details necessary to cultivate, test for viability and store the deposit. If a mixture, provide description of components and a method to check for presence. If a plasmid, provide name of host and antibiotic resistance. Tomato hybrid for bush growth without staking. Seed storage 15°C humidity 50%.

6. Provide sufficient description so that ATCC may confirm deposit properties (e.g., Gram negative rod).

a. If deposit is a cell culture, is it being cultured in the presence of antibiotics? ☐ Yes ☒ No

If yes, please list the antibiotics:

b. If deposit is a hybridoma, what is the isotype of the antibody produced?

7. Safety: Is this strain hazardous to humans? ☐ animals? ☐ plants? ☐

If yes, what is the recommended biosafety level for working with this strain?

(Refer to Biosafety in Microbiological and Biomedical Laboratories, 4th ed. HHS Publication No. (CDC) 93-1395, U.S. Department of Health and Human Services, Centers for Disease Control, Washington, DC, U.S. Government Printing Office, 1999. The entire text is available online at www.cdc.gov/od/ohrt/biosfty/bmbl4/bmbl4a.htm.)

B. Regulatory Compliance

a. Was the material derived from a human? ☐ Yes ☒ No

If yes, was an IRB-approved consent form (human subjects) obtained? ☐ Yes ☒ No

b. Was this material obtained from wildlife? ☐ Yes ☒ No

If yes, please indicate genus and species and whether wild or captive bred:

c. Is work performed at your facility with exotic viruses affecting livestock and avian species? ☐ Yes ☒ No

- d. Identify any reagents of animal origin used to cultivate this organism/cell line (serum, growth factors, trypsin, etc.) and manufacturer, if known:

10. Availability:

Prior to issuance of a U.S. Patent, ATCC will only make a culture available as instructed by the depositor or relevant patent office. Samples must be provided to a specific investigator if a pertinent Patent Office under the Budapest Treaty instructs ATCC to do so. The following questions must be answered:

- a. As of date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to anyone who requests a culture? If yes, there are no restrictions on distribution. Answering no will ensure the deposit is not available until the patent has issued. ☐ Yes ☒ No
- b. As of the date of deposit or conversion to meet the requirements of the Budapest Treaty, do you wish the deposit to be made available to requesters that satisfy Patent Offices in countries not signatory to the Budapest Treaty? ☐ Yes ☒ No
- If Yes, please state which countries:

Please note that if you are converting your deposit to meet the requirements of the Budapest Treaty, and your deposit has already been released for distribution due to the issuance of a U.S. Patent, you cannot restrict it from further distribution.

After a U.S. Patent issues and we are so notified, ATCC makes the culture available to anyone who requests it as allowed under U.S. Patent and Trademark Office (USPTO) Rules and Regulations (37 CFR 1.808 (a)(2)).

11. Notification: ATCC will notify you of your ATCC number after viability of the deposit has been confirmed.

Name of individual to notify: Dr. Shoshan Hara

Fax: 972-8-8800580

Phone: 972-8-8800993

E-mail: shoshan@hazera.com

12. Payment by check or credit card (MasterCard, VISA or American Express) must accompany the deposit unless prior arrangements for billing have been made and approved. ATCC accepts purchase orders for the exact amount.

Money Wire Transfer (2,500\$) by Hazera Genetics Ltd. to the first International Bank of Israel to Account Number: 003933990362, ABA # 052081833, ATCC.

Check No.:

Purchase Order No.:

Credit Card Number:

Please indicate MasterCard, VISA, or American Express:

Exp. Date:

Name shown on card:

(Please print clearly or type)

Signature of cardholder:

Name:

PAYMENT: ATCC MUST HAVE A BILLING ADDRESS, CONTACT PERSON, PHONE AND FAX FOR ALL DEPOSITS.

Contact Name: Assaf Navot

Billing Address: R&D Division, Mishor, M.P. Eshelot derom, 78354, Israel

Phone: 972-8-8878123

Fax: 972-8-8714057

Do you have a current ATCC account number? ☐ Yes ☒ No

If Yes: ATCC Account Number:

If No: To apply for an account with ATCC, please complete a New Account Application located on our Web site (www.atcc.org) and return it with supporting documentation to ATCC for approval.

13. Name, address, phone and fax number of your Attorney of Record:

Contact Name: Dr. Hedva Schickel

Address: Webb & Associates, Patent Attorney, P. O. Box 2189, Rehovot 76121, Israel

Phone: ++972-8-9484666

Fax: ++972-8-9470860

(Ref: Docket or Case No. HZR/001 PCT)

14. **MUST BE COMPLETED.** Deposited on behalf of: (Verify with your management who owns the deposit. The owner is usually a company or institution, and not an individual.) Hazara Genetics Ltd.

I understand and agree that the deposit may not be withdrawn by me for the period specified in Rule 2.1 of the Budapest Treaty (at least 30 years after the date of deposit or 5 years after the date of the most recent request for the deposit, whichever is longer), and that if a culture is lost or is destroyed during the life of the patent or the period of time so specified, it is my responsibility to replace it with a living culture of the same organism or cell. In the case of viruses, cell cultures, plasmids, embryos, and seeds, it is my responsibility to supply a sufficient quantity for distribution for the period of time specified above.

Hazara Genetics Ltd.

Dr. Evaldard - Head of R&D Division

Printed Name

Signature

Date

Address: R&D Division, Minerva M.P. Labs, Dardot - 70354, Israel

Phone: 972 3 8776120

Fax: 972 3 8774057

E-mail: evaldard@hazara.co

SHIPPING INFORMATION

BEFORE SHIPPING, PLEASE CONTACT THE ATCC PATENT DEPOSITORY FOR SHIPMENT ADVICE.

Fax: (703) 365-2745

E-mail: PatentDeposit@atcc.org

SHIPPING NOTICE

The depositor is ultimately responsible for the shipment of deposits to the ATCC and compliance with all applicable government regulations for the packaging and movement of the material. The depositor shall indemnify ATCC to the extent permitted by law, against claims resulting from the violation of applicable government regulations caused by the depositor's shipment of deposits to the ATCC.

STORAGE & FEES

Storage: Cultures are stored for 30 years from date of deposit or five years after the last request for a sample, whichever is longer, as required under the rules of patent offices in most countries.

Fees: All fees are subject to change. For current fees and other information, check our Web site at: www.atcc.org or request a quotation of fees by e-mail at PatentDeposit@atcc.org or fax: (703) 365-2745.

ATCC USE ONLY - ATCC DESIGNATION

REC'D

V-T RESULT

ATCC® is a registered trademark of the American Type Culture Collection.

US 10/587,789**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**In re Application of: **Ezri Peleg**Serial No.: **10/587,789**Attorney Docket No.: **27275.005**Filed: **March 03, 2008**Title: **HIGH LYCOPENE TOMATO VARIETIES AND
USE THEREOF**Examiner: **Bui, Phuong T**Group Art Unit: **1638****DECLARATION**

We the undersigned, Hazera Genetics Ltd., assignee for US Patent Application 10/587,789
do hereby declare that on January 29, 2004 we sent for deposit with ATCC the following seeds:

2500 seeds of *Lycopersicon esculentum* HA3518 designated PTA-5796

This deposit has been made under the Budapest Treaty on the International Recognition of the
Deposit of Microorganisms for the Purposes of Patent Procedure.

We hereby declare that the seeds will be irrevocably and without restriction or condition released
to the public upon issuance of a patent for this application.

Hazera Genetics Ltd.
HAZERA GENETICS LTD

By:

Robert Nedel29/05/2011

Date

29/05/2011

APPENDIX IV



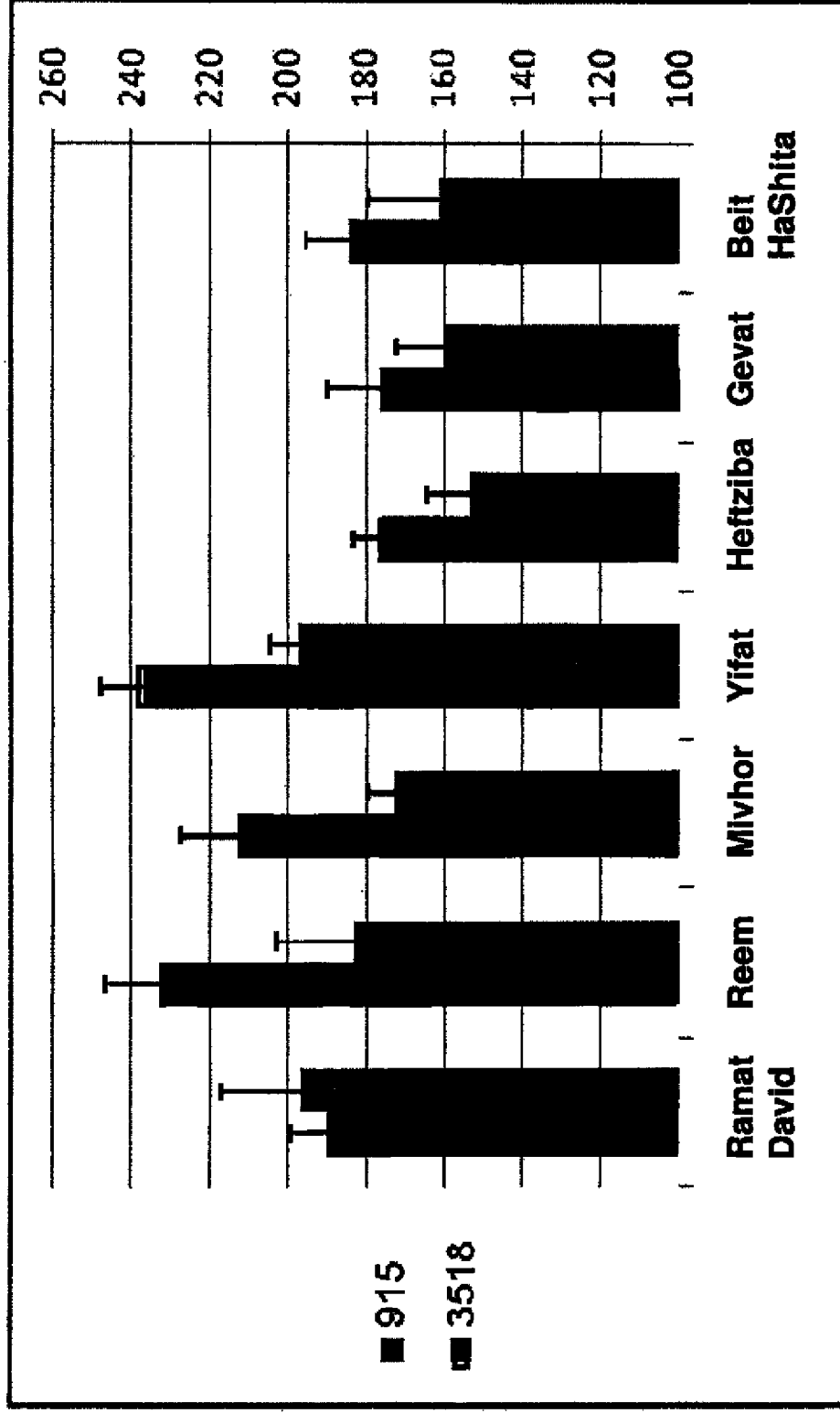
Appendix IV

Comparison between HA3518 and LRT915

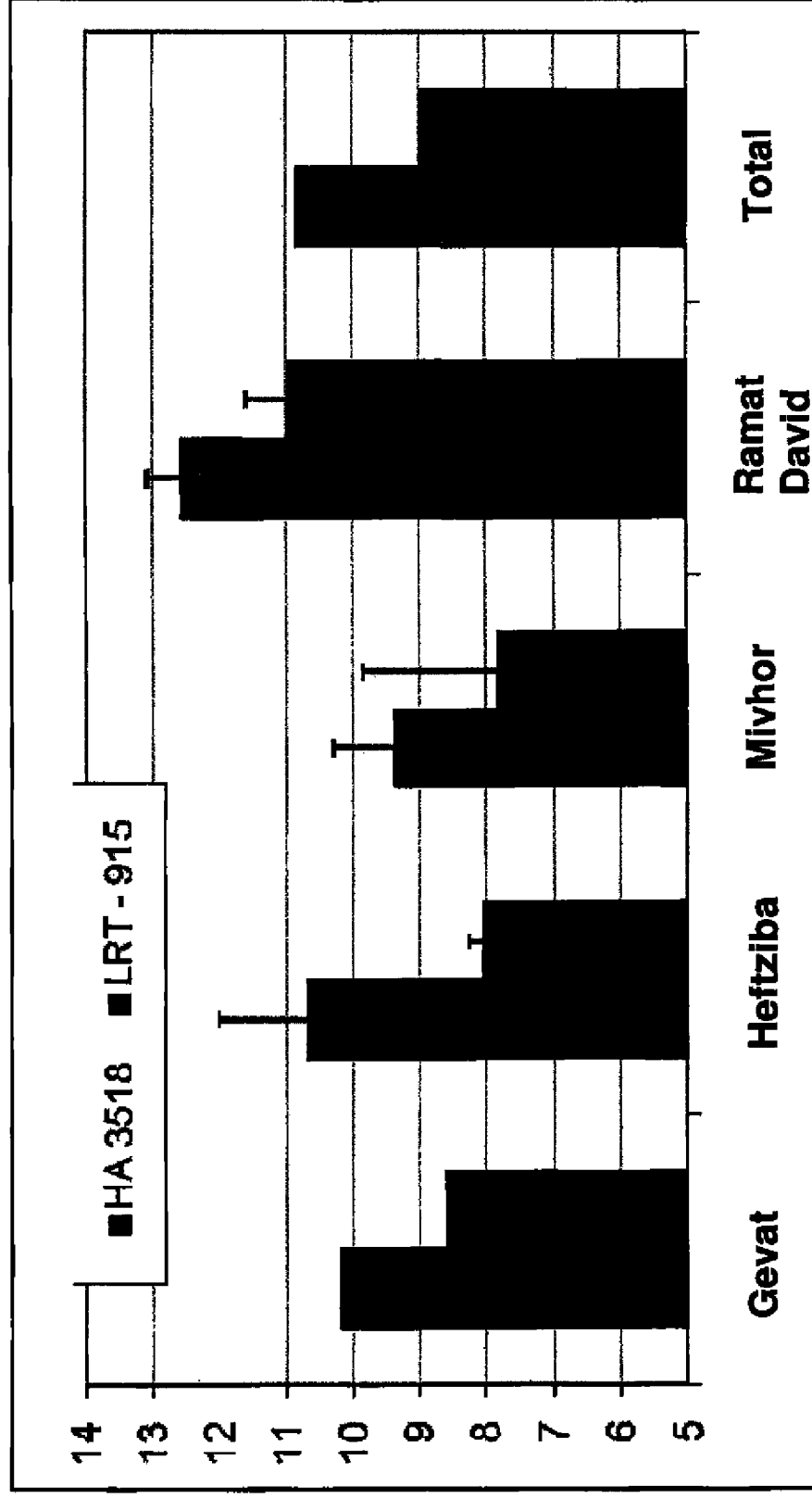
(2002)



Lycopene concentration (ppm)



Fruit Yield (kg/m²)





Summary of Lycopene content at different locations

HA3518 reaches an average (at 11 locations) Lycopene content of 204 ppm.

LRT915 reaches an average Lycopene content of 188 ppm.

The total average Lycopene content of HA3518 is 8% higher than LRT915



Summary of fruit yield at the different locations

HA3518 produces an average (at 8 locations) yield of 9 kg/m²

LRT915 produces an average yield of 7.8 kg/m²

The total average yield of HA3518 is 14.5% higher than LRT915

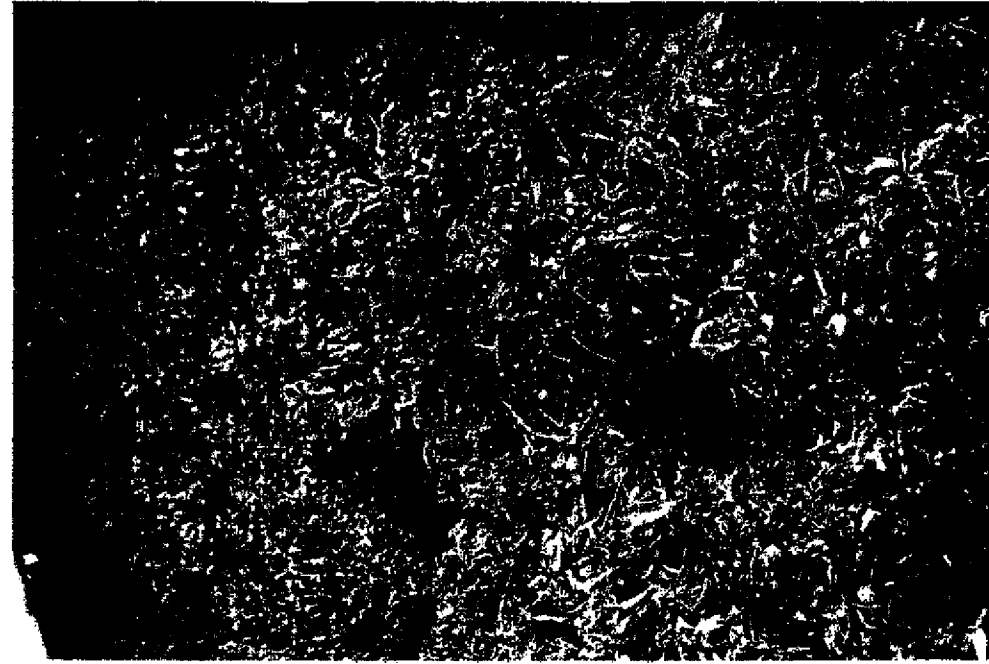


Summary of Lycopene concentration per dunam

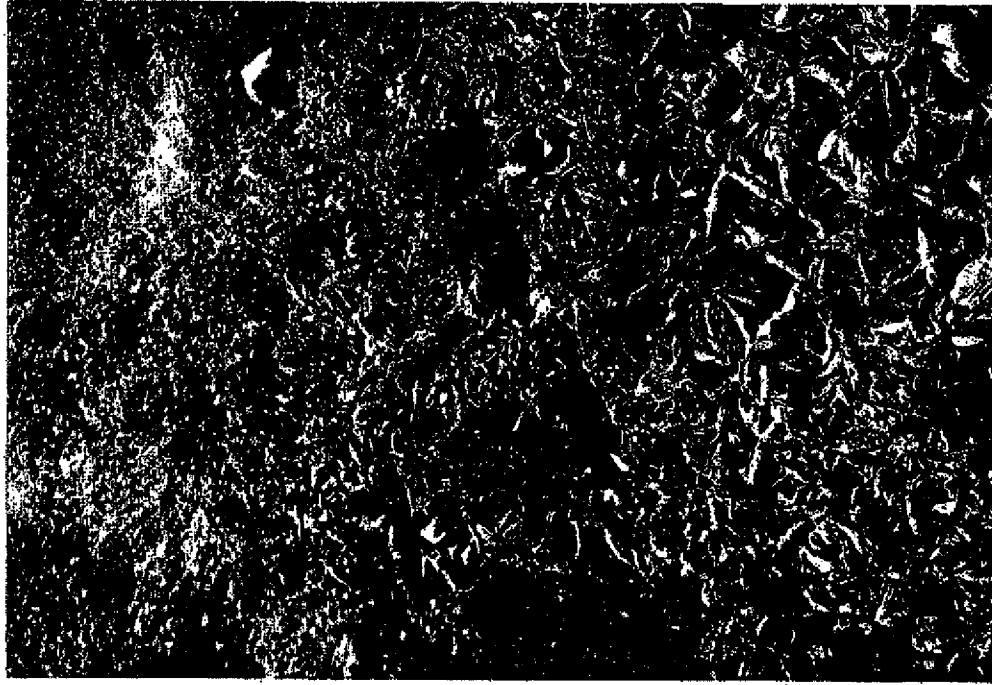
HA3518 has an average (at 8 locations) lycopene per dunam of 1837 ppm/dunam.

LRT915 has an average (at 8 locations) lycopene per dunam of 1481 ppm/dunam.

The lycopene per dunam of HA3518 is 20% higher than LRT915.



LRT915



HA3518

**Table 1: Pleiotropic traits
comparison**

Trait/Phenotype	HA3518	LRT915
Sensitive leaves	-	+
Sudden leaf death	-	+
Brittle stems	-	+
Poor root system	-	+
Premature rotting fruits	-	+ (two weeks earlier)
Seed germination rate	High rate (about 92%)	Lower rate (about 72%)